

formed to be the size of an electrocardiogram (ECG) electrode. The electrode, with its colored hydrogel on the skin-contacting surface thereof, would then be packaged and shipped. The ultimate recipient of the ECG electrode would likely have stored the device in inventory for at least a short period of time thereby potentially exposing the gel to the possibility of dehydration or drying out. In the case of an ECG electrode, this would mean that its electrical conductivity characteristics would be dramatically reduced. When it becomes time for the ECG electrode to be used, all that it is necessary is for the user to visually check the color of the hydrogel on the ECG electrode with its color shortly after first preparation. If the color of the hydrogel at time of use is red as opposed to blue, then the hydrogel material has become dehydrated, and the electrode should not be used. Using this is expedient, the user avoids the potential waste of time and embarrassment of utilizing the biomedical device such as by placing it on the patient's body only to find that the electrical characteristics of the gel are such that the electrode is unusable. Thus in the practice of this invention, wasting of time and embarrassment are avoided.

The invention contemplates a visual comparison between the color of the hydrogel at time of application with its freshly prepared color. The particular manner in which this comparison is made is not critical to this invention. However, a preferred method of comparison has been developed which is particularly applicable to electrosurgery return electrodes. This preferred method contemplates the application of a small transparent piece of water impenetrable tape to a portion of the hydrogel after it is placed on the working surface of the electrode. This water impenetrable transparent tape contains the local state of hydration of the gel beneath it. In this manner a fairly-accurate, visually-comparable sample of the freshly prepared gel is maintained in close proximity to the rest of the hydrogel on the biomedical device.

Alternative means of making the comparison could include a colored picture of the freshly-prepared colored gel which would permit comparison prior to placement of the electrode on the patient's skin. This technique is comparable to that used with pH papers in which the acidity (or basicity) of a material is determined by comparing the pH paper color after testing with a standard color chart. With this teaching in mind, many modifications of the comparison step would be readily apparent to one of ordinary skill in this art.

This invention has been described, in detail, with particular reference to certain preferred embodiments as set forth above. It is to be understood that variations and modifications can be effected within the spirit and scope of this invention.

What is claimed is:

1. A visual method for detecting the state of dehydration of a polymeric gel disposed on the skin-contacting surface of a biomedical device comprising the steps of: selecting a weakly acidic or weakly basic, pH sensitive colored indicator;

preparing the gel by incorporating the selected indicator therein to produce a gel having a first color; applying the first color gel to a skin-contacting surface of a biomedical device; and

shortly before the device is to be used, visually comparing the color of the gel just before used with its first color to determine the relative state of dehydration of the gel.

2. A method according to claim 1 wherein the gel is prepared by the steps of mixing the selected indicator with the gel raw materials.

3. A method according to claim 1 wherein after the first color gel is applied to the skin-contacting surface of the biomedical device a visually transparent humidity barrier is placed on a portion of the gel, and the visual comparison is between a covered and uncovered portion of the gel.

4. A method according to claim 1 wherein the gel has sodium acetate as an electrolyte.

5. A method according to claim 1 wherein the indicator is selected from the group consisting of FD&C Blue #1, FD&C Blue #2, FD&C Green #3, D&C Green #8 or D&C Red #27.

6. A method according to claim 1 wherein the biomedical device is an iontophoresis electrode.

7. A visual method for detecting the state of dehydration of a conductive polymeric hydrogel disposed on the skin-contacting surface of a biomedical device comprising the steps of:

selecting a weakly acidic or weakly basic pH sensitive colored indicator selected from the group consisting of FD&C Blue #1, FD&C Blue #2, D&C Green #3, D&C Green #8 or D&C Red #27; preparing the hydrogel by incorporating the selected indicator therein thereby producing a hydrogel having a first color;

applying the first color hydrogel to a skin-contacting surface of the biomedical device; and

shortly before the device is to be used, visually comparing the color of the hydrogel just before use with its first color to determine the relative state of dehydration of the gel.

8. A method according to claim 7 wherein the hydrogel is prepared by the steps of mixing the selected indicator with the gel raw materials.

9. A method according to claim 7 wherein after the first color gel is applied to the skin-contacting surface of the biomedical device a visually transparent barrier having a low moisture vapor transmission rate is placed on a portion of the gel, and the visual comparison is between a covered and uncovered portion of the gel.

10. A method according to claim 7 wherein the gel comprises sodium acetate.

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